

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN: 8/31/95 OUT: 10/25/95

Reviewed by Michael Nieves Date 10/25/95

LAN Code J. Vautour

EPA Reg. No. or File Symbol 5813-21

EPA Petition or EUP No. None

Date Division Received 8/7/95

Type Product Hospital Disinfectant

MRID No(s) 436958 (1-12) & 437470-1

Product Manager Ruth Douglas (PM 32)

Product Name Tackle

Company Name Clorox

Submission Purpose: This submission is an application to review the revised Master Label with accompanying efficacy data (13 studies).

Type Formulation Liquid

Active Ingredients(s)

Sodium hypochlorite..... 2.0%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

Reviewed by Michael Nieves Date 9/21/95
LAN Code _____
EPA Reg. No. or File Symbol 5813-21
EPA Petition or EUP No. None
Date Division Received 8/7/95
Type Product Hospital Disinfectant
MRID No(s) 436958 (1-12) & 437470-1
Product Manager Ruth Douglas (PM 32)
Product Name Tackle
Company Name Clorox

- 200.0 **Introduction:**
- 200.1 **Uses:**
See label dated June 15, 1995.
- 200.2 **Background Information:**
This submission is an application to review the revised Master Label with accompanying efficacy data (13 studies).
- 200.3 **Factors Affecting Amount/Type of Data Required:**
None
- 201.0 **Data Summary**
None
- 201.1 **Abstract of Test Reports:**
None
- 201.2 **Brief Description of Tests:**
Studies with (MRID 436958 1-12) are titled as follows:
"Efficacy Study # - Tackle EPA Reg. No. 5813-21" by Mark R. Entrup/Bonnie Bowdon of Hill Top Biolabs, Main and Mill Streets, Miamiaville, Ohio 45147. dated March 15 / April 12, 1995)

Study MRID No. 43470-1 is titled: "Efficacy Study # - Tackle EPA Reg. No. 5813-21" by Mark R. Entrup of Hill Top Biolabs, Main and Mill Streets, Miamiaville, Ohio 45147. dated March 15, 1995)
- 201.3 **Data Summaries**
None
- 201.4 **Other Summarized Results:**
See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

1. The submitted efficacy data (MRID No. 436958-1) developed by the AOAC Use Dilution Test Method and AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a Hospital Disinfectant against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella choleraesuis* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538), when sprayed on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 30 seconds at 22°C.

2. The submitted efficacy data (MRID No. 436958-2) developed by the AOAC Use Dilution Test Method and AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a Hospital Disinfectant against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella choleraesuis* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538), at a dilution of 1:32 with 205 ppm AOAC hard water, on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 5 minutes at 20°C.

3. The submitted efficacy data (MRID No. 436958-3) developed by the modified AOAC Use Dilution Test Method and AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a fungicide against *Trichophyton mentagrophytes* CDC y-68+ when used undiluted on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 5 minutes at 20°C.

4. The submitted efficacy data (MRID No. 436958-4) developed by the modified AOAC Use Dilution Test Method and AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a fungicide against *Aspergillus niger* (ATCC 6275) when used undiluted on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 5 minutes at 22.5°C.

5. The submitted efficacy data (MRID No. 436958-5) developed appear adequate to support effectiveness of the product as a virucide against Rhinovirus (VR-1110) when sprayed on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 30 seconds at 26°C.

6. The submitted efficacy data (MRID No. 436958-6) appear adequate to support effectiveness of the product as a virucide against Rhinovirus (VR-1110) on hard, non-porous surfaces when diluted with 210 AOAC hard

water to make a 1:32 dilution in the presence of 5% organic load for a contact time of 5 minutes at 26°C.

7. The submitted efficacy data (MRID No. 436958-7) appear adequate to support effectiveness of the product as a virucide against Human Hepatitis A Virus (HAV-1) on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 30 seconds at 25°C.

8. The submitted efficacy data (MRID No. 436958-8) appear adequate to support effectiveness of the product as a virucide against Human Hepatitis A Virus (HAV-1) on hard, non-porous surfaces when diluted with 205 AOAC hard water to make a 1:32 dilution in the presence of 5% organic load for a contact time of 5 minutes at 26°C.

9. The submitted efficacy data (MRID No. 436598-09) appear to support effectiveness of the product as a virucide against HIV (AIDS Virus) when sprayed on hard, non-porous surfaces in the presence of whole blood for a contact time of 2 minutes at 26°C.

10. The submitted efficacy data (MRID No. 436598-10) appear to support effectiveness of the product as a virucide against HIV-1 (AIDS Virus) on hard, non-porous surfaces at a 1:32 dilution when diluted with 210 ppm AOAC hard water in the presence of whole human blood for a contact time of 5 minutes at 23°C.

11. The submitted efficacy data (MRID No. 436598-11) appear adequate to support effectiveness of the product as a virucide against Influenza A2 Hong Kong (VR-544) when sprayed on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 30 seconds at 26°C.

12. The submitted efficacy data (MRID No. 436598-12) appear to support effectiveness of the product as a virucide against Influenza A2 Hong Kong (VR-544) on hard, non-porous surfaces when diluted with 204 ppm AOAC hard water to make a 1:32 dilution in the presence of 5% organic load for a contact time of 5 minutes at 27°C.

13. The submitted efficacy data (MRID No. 437470-01) developed by the AOAC Use Dilution Test Method and AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a fungicide against *Aspergillus niger* (ATCC 6125) on hard, non-porous surfaces when diluted with 200 ppm AOAC hard water in a 1:16 dilution for a contact time of 5 minutes at 20°C.

Labeling

The proposed labeling is unacceptable. The registrant has submitted a proposed label 19 pages long. Most of the proposed labeling language consists of repeating phrases or words from 10 lists that range from Alternate wording for Disinfection to Surfaces for Disinfecting. The following comments apply to the use of those lists:

1. The use of "**alternate wording for disinfection**" is unacceptable. The registrant must clearly state in the label that the product disinfects. Proposed words such as "eliminates, removes, attacks" are unacceptable.

2. The product label must clearly state that the product is effective when used on **hard, non-porous surfaces**. List 2, **Surfaces for Disinfecting**, contain surfaces that do not fall under this description, e.g. walkways, driveways, drive-throughs.

3. The disinfection instructions lists food contact surfaces (see list 2) such as kitchen utensils and food processors. In such cases the instructions should instruct the user to rinse (with potable water) the surfaces after disinfection.

4. List 5 mentions USDA meat & Poultry Processing Facility & USDA Meat & Poultry Packing Facility. The registrant must submit a evidence from USDA authorizing those label claims.

5. The registrant must list the **complete** name of the microorganism affected by the use of the product e.g. Salmonella choleraesuis, Influenza A2 Hong Kong, HIV-1 virus, etc. Words such as Cold, Flu, Staph. are unacceptable unless accompanied by the full name of the targeted microorganism.

6. On page 6, under the heading "**To Disinfect fungi...**", the registrant must mention the specific microorganism for which data has been developed, in this case: Tricophyton mentagrophytes.

7. On page 7, the instructions for disinfection of HIV-1 are unacceptable. Include the following guidelines for personal protection:

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects and in which the surfaces/objects likely to be soiled with blood or body fluids can be

associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surface wet for X minutes. This contact time will not control other common types of viruses and bacteria.

● The use of the wording "...in whole blood..." is unacceptable.

The following comments apply to the bullets on pages 11 through 16. The following bullets are UNACCEPTABLE:

●Disinfects [As it kills - or alternate list 1 microorganisms list 8] - "As it kills" is unacceptable.

●100% Effective on Germs, Bacteria, Viruses

●All bullets which claim 100% effectiveness.

●All bullets which violate the general comments above e.g. use of alternative language for disinfection, etc.

12. On page 13, the following bullets are unacceptable:

●Sprays away germs

●Hospital Grade Disinfectant and Cleaner (including any variations)

●Bullets that claim "Guaranteed Effectiveness" are unacceptable.

●The use of the words "Grade and Strength" are unacceptable.

On page 14, the following bullets are unacceptable:

- "Virucidal Formula " should read "Virucidal Formula*" indicating the specific viruses which have been tested.

- The USDA recommends ... beef" Please refer to USDA comment above.

- Attach the following EPA/FDA MOU statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surfaces or instrument that (1) is introduced directly into the human body, either into or in contact with bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

Note to PM: Please resubmit corrected label for EETMS review prior to acceptance.